

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

)	
THE UNITED STATES OF AMERICA <i>et al.</i>)	
<i>ex rel.</i> JULIE LONG,)	
)	
Plaintiffs,)	Civil Action No. 16-CV-12182-FDS
)	
v.)	
)	
JANSSEN BIOTECH, INC.,)	
)	
Defendant.)	
)	

**PLAINTIFF-RELATOR'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO COMPEL FULL DISCLOSURE OF LEGAL ADVICE
RECEIVED REGARDING THE LAWFULNESS OF PROVIDING THE
INFUSION BUSINESS SUPPORT AND CONSULTATIVE SERVICES AT ISSUE**

Table of Contents

I.	INTRODUCTION	1
II.	BACKGROUND	2
A.	Janssen’s Alleged Violations Of The Anti-Kickback Statute And False Claims Act	2
B.	One Of The Principal Factual Disputes In This Case Is Whether Janssen Acted Willfully In Violating The AKS	2
C.	Relator’s Earlier Complaint That Janssen Was Using The Attorney-Client Privilege As Both A Sword And Shield	3
III.	ARGUMENT	5
A.	Because Janssen Is Partially Disclosing Legal Advice And Implying That Its Attorneys Reviewed And Concluded That The IOI Support Complied With The AKS, Fairness Requires Full Disclosure Of The Legal Advice It Actually Received	5
B.	Because Janssen Is Asserting An Affirmative Defense That It Had A Good Faith Belief That Providing The IOI Support Did Not Violate The AKS, Fairness Requires Full Disclosure Of The Legal Advice It Received On This Subject	12
C.	Despite Its Statements To The Contrary, Janssen Is Putting Forth A Reliance Upon Counsel Defense And Fairness Requires Full Disclosure Of The Legal Advice It Received Concerning Whether The IOI Support Complied With The AKS	18
IV.	CONCLUSION	20

Table of Authorities

Cases

<i>Arista Records LLC v. Lime Grp. LLC</i> , No. 06-cv-5936, 2011 WL 1642434 (S.D.N.Y. Apr. 20, 2011)	12
<i>Bacchi v. Massachusetts Mutual Life Ins. Co.</i> , 110 F. Supp.3d 270 (D. Mass. 2015)	12, 13, 17, 19
<i>Banco do Brasil, S.A. v. 275 Washington Street Corp.</i> , No. 09-11343, 2011 WL 3208027 (D. Mass. July 27, 2011)	19
<i>Cox v. Administrator U.S. Steel & Carnegie Pension Fund</i> , 17 F.3d 1386 (11th Cir. 1994)	12
<i>Hamilton v. Yavapai Comm. College District</i> , No. CV-12-08193, 2016 WL 8199695 (D. Ariz. June 29, 2016)	13
<i>In re Keeper of the Records (Grand Jury Subpoena Addressed to XYZ Corp.)</i> , 348 F.3d 16 (1st Cir. 2003)	9
<i>In re the County of Erie</i> , 546 F.3d 222 (2d Cir. 2008)	10, 12
<i>John Doe Co. v. United States</i> , 350 F.3d 299 (2d Cir. 2003)	10
<i>Massachusetts Mutual Life Ins. Co. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.</i> , 293 F.R.D. 244 (D. Mass. 2013)	9, 17
<i>Nitinol Med. Tech., Inc. v. AGA Med. Corp.</i> , 135 F. Supp.2d 212 (D. Mass 2000)	20
<i>S.E.C. v. Honig</i> , No. 18-cv-8175, 2021 WL 5630804 (S.D.N.Y. Nov. 30, 2021)	12, 14
<i>United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.</i> , 874 F.2d 20 (1st Cir. 1989)	3
<i>United States v. Bilzerian</i> , 926 F.2d 1285 (2d Cir. 1991)	9, 12
<i>United States ex rel. Calilung v. Ormat Indus., Ltd.</i> , No. 3:14-cv-00325, 2016 WL 4107682 (D. Nev. Aug. 1, 2016)	13

<i>United States v. Gorski</i> , 36 F. Supp.3d 256 (D. Mass. 2014)	9
<i>United States ex rel. Patzer v. Sikorsky Aircraft Corp.</i> , 575 F. Supp.3d 1032, 1043 (E.D. Wis. 2021)	14
<i>United States ex rel. Saldivar v. Fresenius Med. Care Hldgs., Inc.</i> , No. 1:10-cv-1614-AT, 2014 WL 11517840 (N.D. Ga. Feb. 21, 2014)	13

Statutes

31 U.S.C. § 3729	passim
42 U.S.C. § 1320a-7b	passim

Rules

Federal Rule of Evidence 502	10
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I. INTRODUCTION

Plaintiff-relator Julie Long respectfully submits this memorandum of law in support of her motion to compel defendant Janssen Biotech to fully disclose the legal assessments its attorneys performed and legal advice its attorneys provided regarding whether providing the infusion business support and consultative services at issue was lawful and complied with the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b. This request for an implied waiver of the attorney-client privilege is necessary because, in defending against Relator’s claim that it acted willfully in violating the AKS, Janssen is using the attorney-client privilege as both a sword and shield to gain an advantage. Janssen is doing so by partially disclosing select legal advice it received as well as by asserting an affirmative defense that it had a good faith belief that its conduct was lawful while blocking Relator from examining the actual legal reviews and advice it received from its attorneys. Thus, despite its representations, Janssen is defending this action by relying on its counsel’s advice and involvement in the alleged illegal conduct. It would be manifestly unfair and prejudicial to permit Janssen to continue playing both sides of the attorney-client privilege, allowing it to partially disclose legal advice to make unsubstantiated assertions and imply facts that could refute Relator’s allegation that it acted willfully, while preventing Relator from accessing information that would enable her to test and rebut Janssen’s factual assertions and defenses. Alternatively, the Court should preclude Janssen from using in the litigation the approvals from the Promotional Review Committee, which included an attorney, that signed off on Janssen’s provision of the services at issue to physicians, and also strike Janssen’s affirmative defense that it had a good faith belief in the lawfulness of its conduct.

Relator’s counsel conferred with Janssen’s counsel on January 5 in an attempt to resolve this dispute before filing this motion.

II. BACKGROUND

A. Janssen’s Alleged Violations Of The Anti-Kickback Statute And False Claims Act

In this action, Relator, on behalf of the United States, seeks to hold Janssen accountable for defrauding the Medicare program. Relator alleges Janssen did this by engaging in a scheme to induce doctors to prescribe and administer two infusion drugs, Remicade and Simponi ARIA, to Medicare beneficiaries by providing the physicians with illegal remuneration in the form of free infusion business support and consultative services (collectively, “IOI Support”). Janssen provided this IOI Support through its team of Area Business Specialists as well as through outside consultants, such as Xcenda, to select physician practices on an ongoing basis, by helping them open, operate, and grow their in-office infusion suite businesses (“IOIs”). Because the free IOI Support applied broadly to the physicians’ overall infusion businesses, where the doctors infused a variety of drugs in addition to Remicade and Simponi ARIA, these free services provided significant value to the recipients.

By providing this valuable remuneration to physicians to induce prescriptions of its drugs to Medicare beneficiaries, conduct Relator alleges Janssen knew was unlawful, Janssen violated the AKS. Because Medicare does not cover items or services resulting from a violation of the AKS, the bills for reimbursement for Remicade and Simponi ARIA submitted to Medicare by physicians who received the IOI Support constituted false claims under the False Claims Act (“FCA”), 31 U.S.C. § 3729. And because Janssen, through this kickback scheme, caused the submission of the false bills, which Medicare subsequently paid, it violated the FCA.

B. One Of The Principal Factual Disputes In This Case Is Whether Janssen Acted Willfully In Violating The AKS

A defendant must act “willfully” in order for its conduct to violate the AKS. *See* 42 U.S.C. § 1320a-7b(b)(2). Acting willfully means “do[ing] something purposely, with the intent

to violate the law ... do[ing] something purposely that law forbids.” See *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989).

Relator alleges that Janssen provided the valuable IOI Support free of charge in order to influence doctors to prescribe and infuse Remicade and Simponi ARIA despite knowing its conduct violated the AKS. In its defense, Janssen has not merely denied that it knew that its conduct was unlawful. Much differently, Janssen has asserted, as an affirmative defense, that it believed that its conduct was lawful, which, if proved, would rebut Relator’s allegation that Janssen acted willfully, likely defeating the AKS and FCA claims.

C. Relator’s Earlier Complaint That Janssen Was Using The Attorney-Client Privilege As Both A Sword And Shield

In discovery, Janssen has produced numerous documents showing that its internal Promotional Review Committee (“PRC”), which included a lawyer from Janssen’s legal department (“PRC attorney”), reviewed and subsequently approved visual aids, such as slide decks, and other materials that the company utilized in providing the IOI Support¹. Janssen, however, is withholding under a claim of privilege numerous other documents and information concerning the actual legal analyses and assessments of the lawfulness of providing the IOI Support performed by the PRC attorneys and other attorneys in Janssen’s legal department including, most germane to the claims and defenses in this case, whether the IOI Support complied with the AKS.

In January 2022, Relator filed a motion requesting that Janssen be required to disclose the legal advice received concerning whether it was lawful to provide the IOI Support, arguing that Janssen had waived the attorney-client privilege as to these communications by producing

¹ All references to IOI Support herein include the visual aids and other materials Janssen used when providing the free infusion business advisory and support services.

documents that show that the PRC attorney approved the provision of the IOI Support to physicians. *See* Pl.’s Mem. in Support of Mot. to Compel (ECF 264) at 4-14. In opposition, Janssen argued that its production of these documents should not result in a waiver because the PRC approval documents, according to Janssen, do not reveal legal advice but rather only show that Janssen reviewed the IOI Support with the PRC including the PRC attorney. *See* Def.’s Mem. in Opp. to Mot. to Compel (ECF 272) at 2, 6-9, 11. The Court ruled that Janssen did not expressly waive the privilege by producing the PRC approval documents because they “do not appear to disclose the substance of any privileged communication.” Apr. 7, 2022 Order (ECF 303) at 2-3. The Court made clear that this was a “discovery ruling, not a determination of the admissibility of the evidence of the PRC review at trial.” *Id.* at 4. Significantly, the Court also instructed that if Janssen “attempt[s] to use the fact of [the PRC] review in a manner that implies approval of legal counsel” that “might trigger an implied waiver.” *Id.*

As part of her waiver motion, Relator also argued that Janssen had impliedly waived the attorney-client privilege by asserting the affirmative defense that it had a subjective good faith belief that providing the IOI Support was lawful and thereby voluntarily placed in issue legal advice that might disprove its belief. *See* Pl.’s Mem. in Support of Mot. to Compel (ECF 264) at 14-16. Janssen contended that this argument was also incorrect, claiming it is not asserting a good faith belief defense that put its state of mind at issue. Instead, according to Janssen, the affirmative defense it was asserting is that it *acted in good faith*. *See* Def.’s Mem. in Opp. to Mot. to Compel (ECF 272) at 1, 3-5. The Court accepted Janssen’s representation that it was not asserting a defense that it had a good faith belief that its conduct was lawful but was instead asserting a defense that “it acted in good faith by adhering to internal-compliance protocols, which included a legal review[.]” Apr. 7, 2022 Order (ECF 303) at 4. And since it is not

necessary to examine privileged communications to test or rebut an acting in good faith defense that is based on objective facts, the Court held that such defense did not impliedly waive the attorney-client privilege. The Court further qualified and limited its ruling as stated above.

Significant discovery has taken place since those rulings. As explained below, it has become clear that Janssen is doing exactly what it had previously disclaimed – it is partially disclosing legal advice to imply that its attorneys did in fact assess whether the various types of IOI Support violated the AKS and subsequently approved that the services could be provided to select physicians for free. And relatedly, it has become evident that Janssen is asserting an affirmative defense that it had a good faith belief that providing the IOI Support to physicians was lawful and did not violate the AKS.

III. ARGUMENT

A. Because Janssen Is Partially Disclosing Legal Advice And Implying That Its Attorneys Reviewed And Concluded That The IOI Support Complied With The AKS, Fairness Requires Full Disclosure Of The Legal Advice It Actually Received

It has become evident that Janssen is trying to rebut Relator's claim that it acted willfully in violating the AKS by partially disclosing select privileged information to create the appearance that, before providing the IOI Support to targeted physicians, its attorneys reviewed whether the services violated the AKS and determined that they did not. Tellingly, however, Janssen has made these selective disclosures and created this unsubstantiated inference while concealing other information that would reveal the legal assessments that were actually performed and the legal advice it received regarding whether providing the IOI Support violated the AKS. This is a poorly disguised attempt at using the attorney-client privilege as both a sword and shield. Due to Janssen deliberately choosing to disclose selective information about its attorneys' assessments and approvals of the IOI Support, Janssen has waived its right to assert

the attorney-client privilege over the actual assessments performed by the PRC attorneys and other contemporaneous legal advice it received regarding whether providing the IOI Support violated the AKS. Accordingly, Janssen should be ordered to make full disclosure of these formerly privileged communications.

As stated above, the Court denied Relator's earlier motion for a ruling that Janssen waived its attorney-client privilege after accepting Janssen's argument that there was no waiver because the PRC approval materials it disclosed merely showed that it had *reviewed* the legality of the IOI Support with its attorneys. *See* Apr. 7, 2022 Order (ECF 303) at 2-3. The Court credited Janssen's assertion when determining that an express waiver had not occurred. *See id.* Importantly, however, the Court instructed that if Janssen later attempts to use the evidence concerning the PRC reviews in a manner that implies that its attorneys *approved* the provision of the IOI Support to customers, this might trigger an implied waiver. *See id.* at 4.

As discovery has progressed, including depositions of employees with knowledge of the legal assessments conducted by the PRC attorneys as part of the PRC's reviews, it is now evident that Janssen has not merely disclosed that it *reviewed the IOI Support* with its attorneys, Janssen has also disclosed that: (i) one of the main purposes of such legal assessments was for the attorneys to determine whether the IOI Support violated the AKS, and (ii) the *attorneys ultimately approved that the IOI Support could be provided to physicians*. The inference naturally drawn from these disclosed facts is that, during their reviews, the PRC attorneys concluded that providing the IOI Support for free to select physicians did not violate the AKS.

More particularly, Janssen has produced documents and allowed employees to provide deposition testimony evidencing four general facts:

- (1) Janssen reviewed the IOI Support and materials utilized in providing the IOI Support with the PRC including the PRC attorneys;

- (2) One of the purposes of the PRC reviews was for the PRC attorneys to ensure that the IOI Support complied with the law including the AKS;
- (3) The PRC attorneys approved the requests for approval to provide the IOI Support to physicians; and
- (4) Employees believed they could provide the IOI Support because the PRC, including the PRC attorney, approved providing the IOI Support to physicians.

Submitted herewith as Exhibit 1 is a spreadsheet compiling examples of evidence in the form of documents Janssen has produced, Janssen's responses to interrogatories, and testimony Janssen has allowed concerning the above asserted facts. Considered together, these facts strongly imply that the PRC attorneys not only reviewed whether the IOI Support violated the AKS but actually concluded that the IOI Support did not violate the statute. Consequently, the PRC approvals, in combination with the other facts Janssen has disclosed concerning the legal assessments performed by the PRC attorneys, reasonably lead to an inference that the PRC attorneys' approvals communicated their beliefs that providing the IOI Support to physician practices did not violate the AKS thereby making it okay for the services to be provided.² Janssen's employees understood the PRC approvals to be final authorizations to provide the various types of IOI Support, not mere requests to review their lawfulness. *See* Exhibit 1 at p.12 (setting forth examples of evidence that employees believed that they could provide the IOI Support because the PRC, including the PRC Attorney, approved providing the IOI Support to physicians).

Thus, Janssen has not merely disclosed that it *reviewed the legality of the IOI Support* with its attorneys; rather, it has gone much further by also revealing that its attorneys *approved of Janssen providing the IOI Support*, thereby implying that the attorneys had concluded that

² Although obvious, it bears mentioning, that an attorney's communication that conduct is lawful constitutes legal advice regardless of whether it is expressed in a communication solely from that attorney or as part of a communication, such as many of the PRC approval documents Janssen has produced, that also conveys the results of different assessments performed by others.

Janssen's provision of the IOI Support did not violate the AKS. Of course, this inference would not be possible had Janssen not partially disclosed the formerly privileged information that the PRC attorneys approved of Janssen providing the IOI Support.

By disclosing certain legal advice and using it as a sword to gain a benefit in this litigation, Janssen has directly placed that legal advice, as well as other legal advice concerning the same subject, in issue. However, in an effort to prevent Relator from testing and rebutting these disclosed facts and the inferences they create, Janssen has asserted the attorney-client privilege to shield information concerning the actual legal analyses and reviews underlying its PRC attorneys' approvals of the IOI Support. Discovery of the actual legal assessments that the PRC attorneys conducted before approving the IOI Support is essential to testing the accuracy of the facts Janssen is asserting and implying. For instance, disclosure of the actual legal reviews underlying the PRC attorneys' approvals might reveal that: (i) the attorneys approved providing the IOI Support without actually reviewing whether doing so would violate the AKS; (ii) the attorneys reviewed the IOI Support for compliance with the AKS but were not apprised of material facts concerning the IOI Support, causing their approvals to be incorrect and/or unreliable; (iii) the attorneys knew that the IOI Support violated the AKS but approved it anyway; and/or (iv) the attorney lacked the expertise or competence to be able to provide reliable legal advice concerning the AKS. Likewise, Janssen has also improperly asserted the attorney-client privilege to withhold documents and prevent witnesses from providing information concerning reviews and analyses performed by its attorneys outside of a PRC review concerning whether the IOI Support violated the AKS.³

³ There is evidence that Janssen's legal department also reviewed the legality of the IOI Support through assessments that were conducted separate from the PRC reviews. *See, e.g.*, Tr. of T. Cornely Dep. 187:5-187:23 (Exhibit 6).

Janssen’s tactics are a textbook example of using the attorney-client privilege as both a sword and shield. An implied waiver should result because Janssen cannot be permitted to partially disclose legal advice to its advantage. *See In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003) (“Implying a subject matter waiver in such a case ensures fairness because it disables litigants from using the attorney-client privilege as both a sword and a shield. Were the law otherwise, the client could selectively disclose fragments helpful to its cause, entomb other (unhelpful) fragments, and in that way kidnap the truth-seeking process.”).

An implied waiver results when “the party asserting the privilege place[s] protected information in issue for personal benefit through some affirmative act, and the court [finds] that to allow the privilege to protect against disclosure of that information would [be] unfair to the opposing party.” Apr. 7, 2022 Order (ECF 303) at 2 (quoting *In re Keeper of Recs.*, 348 F.3d at 24). At the center of an implied waiver determination is the notion of unfairness to the adversary. *See United States v. Gorski*, 36 F. Supp.3d 256, 268 (D. Mass. 2014) (Saylor, C.J.) (instructing that, in determining whether an implied waiver has been triggered, “[t]he touchstone is fairness; a defendant cannot put his attorney’s advice or involvement at issue in a case and then claim a privilege as to the details of that advice or involvement.”). Some courts, including this Court, assess whether “the claims and defenses are so ‘enmeshed’ in privileged evidence that it would be unfair to withhold the material.” Apr. 7, 2022 Order (ECF 303) at 3 (citing *Massachusetts Mut. Life Ins. Co. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 293 F.R.D. 244, 249 (D. Mass. 2013)); *see also United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) (“[T]he privilege may implicitly be waived when defendant asserts a claim that in fairness requires examination of protected communications.”). In assessing whether fairness requires an implied waiver, courts

must consider “the type of unfairness to the adversary that results in litigation circumstances when a party uses an assertion of fact to influence the decisionmaker while denying its adversary access to privileged material potentially capable of rebutting the assertion.” *In re Cty. of Erie*, 546 F.3d 222, 229 (2d Cir. 2008) (quoting *John Doe Co. v. United States*, 350 F.3d 299, 306 (2d Cir. 2003)). Here, the prejudice and unfairness resulting from Janssen’s partial disclosures of legal advice, and the facts reasonably inferred from those disclosures, are significant, as they go directly to one of the critical issues in the litigation – whether Janssen knew it was unlawful to provide the IOI Support free of charge to select physician practices.

Federal Rule of Evidence 502 likewise requires that Janssen’s waiver of the attorney-client privilege extend to all undisclosed privileged communications and legal advice concerning its review of whether the IOI Support violated the AKS. That Rule provides:

When the disclosure is made in a federal proceeding ... and waives the attorney-client privilege or work-product protection, the waiver extends to an undisclosed communication or information in a federal or state proceeding only if:

- (1) the waiver is intentional;
- (2) the disclosed and undisclosed communications or information concern the same subject matter; and
- (3) they ought in fairness to be considered together.

FRE 502(a). The Advisory Committee Notes explain that the rule addresses those situations, like this one, in which “fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary.” Notes to FRE 502(a). Under the rule, “a party that makes a selective, misleading presentation that is unfair to the adversary opens itself to a more complete and accurate presentation.” *Id.*; see also Statement of Congressional Intent, 154 Cong. Rec. H7818-7819, Sept. 8, 2008, 2008 WL 4133109 (noting that the rule addresses “when a party’s strategic use in litigation of otherwise privileged information obliges that party to waive the privilege regarding

other information concerning the same subject matter so that the information can be fairly considered in context”).

In its April 7, 2022 Order, the Court specifically instructed that if Janssen “attempt[s] to use the fact of [the PRC] review in a manner that implies approval of legal counsel ... [that] might trigger an implied waiver.” Apr. 7, 2022 Order (ECF 303) at 4. It is now clear that Janssen is implying, if not expressly asserting, that its attorneys approved of Janssen providing the IOI Support after purportedly concluding that doing so did not violate the AKS. As a result of its selective and misleading assertions, Janssen has impliedly waived the attorney-client privilege.

Moreover, because Relator cannot test or rebut the inference Janssen has created without examining the actual legal reviews performed and legal advice received, Relator’s claims and Janssen’s affirmative defense are enmeshed in privileged communications concerning whether Janssen’s attorneys advised that providing the IOI Support was lawful and in compliance with the AKS. Also, because there is evidence that an integral component of the PRC’s various approvals of the IOI Support were the assessments performed by the PRC attorneys regarding the lawfulness of providing the IOI Support, including whether it violated the AKS, if Janssen is permitted to continue to assert that the PRC approvals do not communicate legal advice that would sanction a misleading portrayal of those approvals and their significance to the employees. The PRC attorneys’ involvement and the role their legal reviews played in the PRC approvals cannot simply be ignored or covered up.

It would be manifestly unfair for Janssen to selectively present evidence of its attorneys’ reviews and approvals to create inferences that the PRC attorneys reviewed whether the IOI Support violated the AKS and subsequently approved the provision of the IOI Support because they concluded that the IOI Support did not violate the statute, while depriving Relator of the

opportunity to test and rebut these asserted facts and inferences that are highly relevant to the willfulness element of Relator's claims as well as Janssen's affirmative defense that it had a good faith belief that providing the IOI Support did not violate the AKS, a defense that Janssen is, in fact, asserting. Alternatively, the Court should preclude Janssen from using the PRC approvals to support any defense in this action.

B. Because Janssen Is Asserting An Affirmative Defense That It Had A Good Faith Belief That Providing The IOI Support Did Not Violate The AKS, Fairness Requires Full Disclosure Of The Legal Advice It Received On This Subject

When a defendant asserts a defense that it had a good faith belief in the lawfulness of its actions, an implied waiver will likely be necessary because “the plaintiff, in order to test the assertion of good faith, would need to know whether the defendant received any legal advice suggesting that its actions were in fact not lawful.” *Bacchi v. Mass. Mut. Life Ins. Co.*, 110 F. Supp.3d 270, 276 (D. Mass. 2015) (citing *In re Cty. of Erie*, 546 F.3d at 229). Said differently, “it would be unfair for a party asserting contentions [of good faith belief in the lawfulness of its actions] to then rely on its privileges to deprive its adversary of access to material that might disprove or undermine the party’s contentions.” *S.E.C. v. Honig*, No. 18-cv-8175, 2021 WL 5630804, at *11 (S.D.N.Y. Nov. 30, 2021) (quoting *Arista Recs. LLC v. Lime Grp. LLC*, No. 06-cv-5936, 2011 WL 1642434, at *3 (S.D.N.Y. Apr. 20, 2011)); *see also Bilzerian*, 926 F.2d at 1292-94 (holding if a defendant presents “testimony that he thought his actions were legal [then he] would have put his knowledge of the law and the basis for his understanding of what the law required in issue” and would therefore be required to disclose privileged communications regarding the legality of his conduct.); *Cox v. Adm’r U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1419 (11th Cir. 1994) (holding that a party that goes beyond mere denial and asserts an affirmative defense that it believed its actions were lawful “inject[s] the issue of its

knowledge of the law into the case and thereby waive[s] the attorney-client privilege,” as “it would be inequitable, to allow [a defendant] to present evidence tending to show that it intended to comply with the law, while allowing it to cloak in privilege those documents tending to show it might have known its actions did not conform to the law.”); *United States ex rel. Calilung v. Ormat Indus., Ltd.*, No. 3:14-cv-00325, 2016 WL 4107682, at *4 (D. Nev. Aug. 1, 2016) (holding that asserting a defense of good faith belief in the lawfulness of its conduct went “beyond mere denial of scienter to put its state of mind and knowledge of the [statutory] requirements at issue,” resulting in a waiver); *Hamilton v. Yavapai Comm. College Dist.*, No. CV-12-08193, 2016 WL 8199695, at *2 (D. Ariz. June 29, 2016) (finding “where the Defendants assert their subjective good faith with respect to a matter of legal compliance, as the Defendants do here, a determination of such subjective good faith may depend on the advice given the Defendants by their counsel,” triggering waiver of the privilege); *United States ex rel. Saldivar v. Fresenius Med. Care Hldgs., Inc.*, No. 1:10-cv-1614-AT, 2014 WL 11517840, at *2 (N.D. Ga. Feb. 21, 2014) (holding that by asserting an affirmative defense that it had a good faith belief that its conduct was lawful defendant waived the privilege because “allow[ing] [defendant] to argue its good faith belief that its conduct was legal, but deny the Relator an opportunity to explore [defendant’s] belief would prejudice the Relator and thus be manifestly unfair.”).

Not every good faith defense places the advice the defendant received from its counsel in issue. Courts distinguish good faith defenses that implicate a defendant’s knowledge of the law from a good faith defense that is based on a defendant’s knowledge of objective facts. *See Bacchi*, 110 F. Supp.3d at 277 (holding that an implied waiver was not warranted because the defendant had not asserted a good faith defense that put in issue its understanding of the law but rather asserted a defense that it acted in good faith and intended to prove the defense by merely

presenting objective facts concerning the steps it took to comply with the law); *Honig*, 2021 WL 5630804, at *12 (observing that not every good faith defense implicates the defendant’s knowledge of the law) (citing cases); *United States ex rel. Patzer v. Sikorsky Aircraft Corp.*, 575 F. Supp.3d 1032, 1043 (E.D. Wis. 2021) (finding that a defendant does not place advice of counsel at issue whenever it alleges “good faith” as part of a defense; rather, “at issue waiver will occur only when the defendant claims that it has a good-faith belief that its conduct was legal”).

And so, when a defendant asserts a defense that it acted in good faith to comply with a legal or contractual requirement, such defense is normally based on objective facts and likely would not implicate the defendant’s knowledge of the law and, in that case, it may not be necessary for the plaintiff to examine the defendant’s privileged communications. On the other hand, when a defendant asserts that it had *a good faith belief in the lawfulness of its actions* and had reviewed the conduct with its counsel, as is the case here, the plaintiff must be given access to the privileged communications, otherwise she has no way to test or rebut the asserted belief.

Here, it has become clear that, contrary to its assertions in opposing Relator’s original motion, Janssen is in fact asserting an affirmative defense that, at the time that it was providing the IOI Support, it had a good faith belief that the services were lawful and did not violate the AKS or FCA. Janssen’s assertion of this affirmative defense triggers an implied waiver of its privilege because Relator has no way of testing or rebutting this defense unless she is able to examine the privileged communications and legal advice Janssen had received concerning whether providing the IOI Support violated the AKS or FCA.

More particularly, Janssen’s 14th affirmative defense alleges, “Relator’s claims for relief are barred, in whole or in part, because any and all actions taken by Janssen with respect to any of the matters alleged by Relator were taken in good faith and in accordance with established

industry practice.” Def.’s Ans. to 2d Am. Compl. (ECF 83) at p.52. Because this affirmative defense is vague, Relator asked Janssen in an interrogatory “whether you contend that when you provided each of the various types of IOI Support and IOI Support Programs that you had a good faith belief that your actions did not violate any law, statute, or regulation.” *See* Def.’s Resp. to Interrog. 20, a copy of which is provided herewith as Exhibit 2 at p.35. In its answer to the interrogatory, which Relator had to file multiple motions to compel to obtain⁴, Janssen clarified that it is asserting a good faith belief defense. In relevant part, Janssen answered: “At the time the product support services were provided, and through the present, ***Janssen had a good faith belief that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute and False Claims Act.***” *See id.* (Exhibit 2 at p.37) (emphasis added).

As discussed above, there is evidence that Janssen not only reviewed the IOI Support with its attorneys and that, as part of their reviews, the attorneys (if they followed policy) would have assessed whether the IOI Support complied with the AKS. *See* Exhibit 1 at p.7 (setting forth examples of evidence that one of the purposes of PRC reviews was for the PRC attorneys to ensure that the IOI Support complied with the law including the AKS). As also discussed above, Janssen has disclosed that the PRC attorneys approved of providing the IOI Support to customers in order to imply that the PRC attorneys: (i) did in fact review whether that IOI Support violated the AKS, and (ii) concluded that the IOI Support did not violate the AKS. *See* Exhibit 1 at p.10 (setting forth examples of evidence that the PRC attorneys approved the requests for approval to provide the IOI Support to physicians). Additionally, there is evidence indicating that Janssen

⁴ *See* Relator’s motions to compel dated February 16, 2022 (ECF 278-280), April 5, 2022 (ECF 306-307), and December 15, 2022 (ECF 345-346).

also reviewed the legality of providing the IOI Support with its attorneys outside the context of the PRC reviews. *See* footnote 3 above. Indeed, Janssen's privilege log exceeds 4,200 entries. Janssen cannot be permitted to assert an affirmative defense that it believed it was lawful to provide the IOI Support and at the same time deprive Relator of access to the actual legal assessments that the PRC attorneys performed and other legal advice Janssen received concerning whether the IOI Support violated the AKS that might disprove or undermine Janssen's asserted belief.

Further, in responding to Interrogatory 20's request for the bases for its defense that it had a good faith belief that providing the IOI Support to physicians was lawful and complied with the AKS, Janssen identified information that either constitutes legal advice or shows the involvement of its counsel as being among the bases for this affirmative defense. Among the bases for its good faith belief are the reviews conducted by the PRC attorneys:

Janssen also had a Promotional Review Committee ("PRC"). As stated in Janssen policy documents, the role of the PRC was to "review[] all promotional materials to ensure medical accuracy and regulatory compliance with applicable laws, regulations and guidelines." JANSSENBIO-018-00001322 at 1322. Janssen has produced Standard Operating Procedures for the PRC, which outline the roles of various committee members and the processes underlying the committee's review. ...

The PRC included members from various Janssen departments, including HCC Regulatory, HCC Privacy, Legal, and Medical. ... According to the PRC SOP, the role of the Legal PRC reviewer was to "[e]nsure[] that PRC reviewed materials comply with applicable state and federal laws and Corporate Policy, including, but not limited to, those related to FDA advertising and promotion, Medicare and Medicaid requirements, Health Care Compliance, False Claims Act, Lanham Act, fraud and abuse laws and product liability." *Id.* at 1269.

Def.'s Resp. to Interrog. 20 effectively incorporating and relying on Def.'s Resp. to Interrog. 3 (Exhibit 2 at p.39). In its response to Interrogatory 20's request for the bases of its good faith belief, Janssen also incorporates a list, which was appended to the response as "Appendix B," of several PRC approvals of the IOI Support, many of which set forth the PRC attorneys'

approvals. *See* Def.'s Resp. to Interrog. 20 effectively incorporating and relying on the PRC approval documents listed in Appendix B to the response (Exhibit 2 at p.39 and Appx. B). Additionally, Janssen has identified other bases for its good faith belief that it was lawful to provide the IOI Support that inherently implicate legal advice and the involvement of its counsel, including: (i) the text of the AKS, relevant case law, HHS guidance, and HHS-OIG Advisory Opinions; and (ii) the asserted facts that it purportedly disclosed it was providing the free services at issue to the Government in response to an earlier investigation and the Government ended the investigation without taking any action (Janssen identified two in-house counsel with knowledge of the investigation). *See* Def.'s Resp. to Interrog. 20 (Exhibit 2 at pp.37, 39-40).

It follows that Janssen has taken the affirmative step of putting privileged information in issue that is highly relevant and potentially disproves the willfulness element of Relator's AKS claims. Janssen's assertion that it had a good faith belief that providing the IOI Support was lawful, voluntarily putting privileged information and its state of mind in issue, while depriving Relator access to material and information that might disprove its contention, is a clear use of the attorney-client privilege as a sword and shield to gain an advantage in the litigation. Relator has no way of testing or rebutting Janssen's asserted belief that providing the IOI Support to targeted physician practices did not violate the AKS, unless she is provided access to the privileged communications and legal advice Janssen received concerning whether the IOI Support complied with the AKS. *See Bacchi*, 110 F. Supp.3d at 276. In other words, Janssen's defense as to its good faith belief in the lawfulness of its actions is so enmeshed in privileged evidence that it would be unfair to allow it to withhold the privileged materials that might disprove the contention. *See Massachusetts Mut. Life Ins. Co. v. Merrill Lynch*, 293 F.R.D. at 249. If Relator is blocked from obtaining discovery of the actual assessments the PRC attorneys performed and

legal advice Janssen received concerning whether providing the free services to select physicians complied with the AKS, then Janssen will be able to unfairly assert an unsubstantiated defense, the truthfulness of which is immune from challenge. Accordingly, the Court should rule that Janssen has impliedly waived the attorney-client privilege regarding the legal advice it received concerning whether providing the IOI Support violates the AKS. Alternatively, Janssen's good faith belief defense should be stricken.

C. Despite Its Statements To The Contrary, Janssen Is Putting Forth A Reliance Upon Counsel Defense And Fairness Requires Full Disclosure Of The Legal Advice It Received Concerning Whether The IOI Support Complied With The AKS

When it was ordered to advise Relator and the Court regarding whether it is going to assert an advice of counsel defense in this action (*see* Oct. 28, 2021 Order (ECF 205) and Nov. 29, 2021 Order (ECF 220)), if Janssen had expressly stated that it is going to rely upon advice it received from its counsel concerning whether providing the IOI Support violated the AKS, then it would have overtly waived the attorney client-privilege and been required to turn over all legal advice it received on this critical issue. In an obvious effort to avoid this consequence and prevent the decisionmaker in this action from seeing that advice, Janssen has been representing that it is not asserting such a defense.

But Janssen's actions belie its representations: Although Janssen has stated that it is not asserting a reliance upon counsel defense, Janssen is partially disclosing legal advice by revealing information concerning its counsel's approvals of the IOI Support (*see* Part III-A above). And although Janssen has stated that it is not asserting a reliance upon counsel defense, Janssen is asserting as an affirmative defense that it had a good faith belief that providing the IOI Support complied with the AKS, an assertion that puts directly in issue its attorneys' assessments and other legal advice it received concerning whether providing the IOI Support violated the

AKS (*see* Part III-B above). And although Janssen has stated that it is not asserting a reliance upon counsel defense, during a hearing, Janssen's counsel touted that the PRC approvals were one of the bases for the company's belief that its conduct was lawful and stated that it would be relying upon the PRC reviews and approvals when it seeks summary judgment:

THE COURT: There's no way I can decide intent or scienter on summary judgment unless it's really at the extremes, right, I mean –

MR. POSNER: Well, the intent standard under the federal anti-kickback statute is a demanding one, and it is on the edge of, I mean, you know, what the government would have to show in a kickback case is a tough and tense standard, and, you know, ***given that these programs went through a top flight, you know, Johnson & Johnson level promotional review committee***, that's going to be a question for your Honor, but this is one that in our view is going to be, you know, really at the edge giving that demanding standard, but that's a question for your Honor.

Oct. 1, 2021 Hearing (ECF 186) at 24:17-22 (emphasis added).

Accordingly, despite Janssen's equivocation, it is evident that it is relying on selectively disclosed portions of legal advice in the form of the PRC attorneys' approvals allowing Janssen to provide the IOI Support to physicians and the inferences reasonably drawn from such approvals in defending against Relator's claim that it willfully violated the AKS. Because Janssen is relying upon advice of counsel, albeit in a furtive manner, Janssen has put at issue its privileged communications concerning whether providing the IOI Support violated the AKS and has thereby impliedly waived the attorney-client privilege concerning those communications. *See Bacchi*, 110 F. Supp.3d at 275 (quoting *Banco do Brasil, S.A. v. 275 Washington Street Corp.*, No. 09-11343, 2011 WL 3208027, at *3 (D. Mass. July 27, 2011)) ("The classic example [of an implied waiver] is where a defendant defends itself against a claim on the ground that it relied on the advice of counsel in performing or failing to perform the challenged conduct. In such a case, the defendant voluntarily puts its attorney's advice at issue and fairness dictates that the opposing party should be able to discover all the attorney's communications on the particular subject, not

just the advice that is helpful to the defendant.”); *Nitinol Med. Tech., Inc. v. AGA Med. Corp.*, 135 F. Supp.2d 212, 217 (D. Mass 2000) (internal citation omitted) (“the deliberate injection of the advice of counsel into a case waives the attorney-client privilege ... because a “party should not be allowed to rely on self-serving documents in its defense while withholding potentially damaging information under the guise of the attorney-client privilege.”).

IV. CONCLUSION

For the reasons set forth above, the Court should rule that Janssen has waived the attorney-client privilege with regard to the assessments concerning whether providing the IOI Support violated the AKS that its attorneys performed and the advice its attorneys provided before and/or while Janssen provided the IOI Support to physicians. Alternatively, the Court should: (i) preclude Janssen from using in the litigation the approvals from the Promotional Review Committee, which included an attorney, that authorized the company to provide the IOI Support to physicians, and (ii) strike Janssen’s affirmative defense that it had a good faith belief in the lawfulness of its conduct.

Relator requests oral argument on this motion.

Dated: January 24, 2024

Respectfully submitted,

/s/ Casey M. Preston

Casey M. Preston (admitted pro hac vice)

Gary L. Azorsky (admitted pro hac vice)

Jeanne A. Markey (admitted pro hac vice)

Adnan Toric (admitted pro hac vice)

COHEN MILSTEIN SELLERS & TOLL PLLC

100-120 N. 18th Street, Suite 1820

Philadelphia, PA 19103

(267) 479-5700

cpreston@cohenmilstein.com

gazorsky@cohenmilstein.com

jmarkey@cohenmilstein.com

atoric@cohenmilstein.com

Theodore J. Leopold (admitted pro hac vice)
Leslie M. Kroeger (admitted pro hac vice)
Diana L. Martin (admitted pro hac vice)
Poorad Razavi (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
11780 U.S. Highway One, Suite N500
Palm Beach Gardens, FL 33408
(561) 515-1400
tleopold@cohenmilstein.com
lkroeger@cohenmilstein.com
dmartin@cohenmilstein.com
prazavi@cohenmilstein.com

Jonathan Shapiro (BBO No. 454220)
SHAPIRO & TEITELBAUM LLP
55 Union Street, 4th Floor
Boston, MA 02108
(617) 742-5800
jshapiro@jsmtlegal.com

Counsel for Plaintiff-Relator Julie Long

Certificate of Service

I hereby certify on this 24th day of January, 2024, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Casey M. Preston
Casey M. Preston (admitted pro hac vice)